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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/07/2003 15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/747,385	ATTARIAN ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4,11,15-20,26,37-40,49,50,55-57,59 and 62* is/are allowed.

6)☒ Claim(s) *5,7,8,10,12,13,21,24,25,27,30-36,41,44-48,51-54,58 and 61* is/are rejected.

7)☒ Claim(s) *6,9,14,22,23,28,29,42,43,60 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of a reply, filed March 22, 2002 as Paper No. 9, to the previous Office Action. Amendments were made to the claims. Acknowledgement is also made of a response to two Non-responsive Office Actions.

Claims 1-63 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed September 11, 2001 as Paper No. 5, that is not addressed in this action has been withdrawn.

Drawings

New corrected drawings are required in this application because of the reasons set forth by the Draftsperson in the attached from PTO-948. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

Claim 63 is objected to because of the following informalities: claim 63 is identical to claim 62, and therefore represents a duplicate claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 33-36, 48 and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for the reasons set forth in the previous Office Action, but is now applied to claim 10, 33-34 and 60, which were inadvertently excluded from the rejection but still require a deposit of the particular plasmid in order to make and use the invention.**

Claims 5, 7, 8, 12, 13, 21, 24, 25, 27, 30-32, 41, 44-47, 51-54, 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection that is not necessitated by amendment.**

Applicant claims nucleic acids, proteins, plasmids or expression vectors comprising or encoding a functional *F. nucleatum* RepA protein with 80% (or in some cases 97%) identity to a protein represented as SEQ ID NO: 1. The claims read on a broad genus of nucleic acids, proteins, plasmids or expression vectors comprising or encoding a broad genus of RepA proteins that are functional in *F. nucleatum*.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by

disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims nucleic acids, proteins, plasmids or expression vectors comprising or encoding a functional *F. nucleatum* RepA protein with 80% (or in some cases 97%) identity to a protein represented as SEQ ID NO: 1 by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings concerning a protein identified as SEQ ID NO: 1. The specification does not identify the domains or portions of the protein that are required for its functionality in *F. nucleatum*. Thus, the skilled artisan cannot envision a sufficient number of functional *F. nucleatum* RepA proteins of the instant invention from the instant specification, because the skilled artisan cannot envision where the amino acid sequence of SEQ ID NO: 1 can be manipulated while retaining its function. As a result, the skilled artisan could not envision nucleic acids, proteins, plasmids or expression vectors comprising or encoding a functional *F. nucleatum* RepA protein with 80% (or in some cases 97%) identity to a protein represented as SEQ ID NO: 1.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of RepA proteins that are functional *F. nucleatum* in by disclosing structural or functional features of an *F. nucleatum* RepA protein so that one of skill

in the art could envision the claimed invention. In fact, the prior art demonstrates that predicting function based simply on sequence homology is unpredictable. For instance, Everett *et al.* (*Nat. Gen.* **17**: 411-422, 1997; see entire document; henceforth Everett) first identified the Pendred gene product PDS, and predicted that PDS would function as a Sulphate-Ion transporter, based on its homology to known Sulphate-Ion transport proteins (see for example the Abstract and page 419, paragraph bridging the left and right columns to the second full paragraph, right column). However, Scott *et al.* (*Nat. Gen.* **21**: 440-443, 1999; see entire document; henceforth Scott) found that PDS was in fact not a Sulphate-Ion transporter despite its homology to known Sulphate-Ion transporters (see for example the Abstract and page 441, left column, third full paragraph). Rather, Scott found that PDS was a Chloride- and Iodide-Ion transporter, underscoring the importance of establishing a function for a protein despite homology with a protein of known-function (see for example the Abstract and page 441, left column, third full paragraph). Thus, the skilled artisan cannot rely on the prior art to envision a sufficient number of nucleic acids, proteins, plasmids or expression vectors comprising or encoding RepA proteins that are functional in *F. nucleatum* to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of nucleic acids, proteins, plasmid or expression vector comprising or encoding a functional *F. nucleatum* RepA protein with 80% (or in some cases 97%) identity to a protein represented as SEQ ID NO: 1. In fact, the prior art teaches the unpredictability associated with trying to associate a structure-function relationship based simply on homology of one protein to another protein of known function. As a result, the

skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 5, 7, 8, 12, 13, 21, 24, 25, 27, 30-32, 41, 44-47, 51-54, 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection that is not necessitated by amendment.**

Applicant claims nucleic acids, proteins, plasmids or expression vectors comprising or encoding a protein that can be bound by polyclonal antibodies which recognize a protein encoded as SEQ ID NO: 1. The claims read on a broad genus of nucleic acids, proteins, plasmids or expression vectors comprising or encoding an *F. nucleatum* RepA protein that is recognized by polyclonal antibodies to a protein represented as SEQ ID NO: 1.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not

sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims nucleic acids, proteins, plasmids or expression vectors comprising or encoding an *F. nucleatum* RepA protein that is recognized by polyclonal antibodies to a protein represented as SEQ ID NO: 1 by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings concerning a protein identified as SEQ ID NO: 1, which can be bound by polyclonal antibodies raised against it. There are no teachings regarding what polyclonal antibodies will specifically or selectively bind to a functional *F. nucleatum* RepA protein, and no teachings as to how to discern what proteins that are bound by such polyclonal antibodies are functional *F. nucleatum* RepA proteins. As a result, the skilled artisan cannot envision a sufficient number of nucleic acids, proteins, plasmids or expression vectors comprising or encoding functional *F. nucleatum* RepA proteins that will be bound by polyclonal antibodies to a protein represented as SEQ ID NO: 1.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of functional *F. nucleatum* RepA proteins that can be recognized by polyclonal antibodies to a protein represented as SEQ ID NO: 1 by disclosing structural or functional features of a functional *F. nucleatum* RepA protein so that one of skill in the art could envision the claimed invention. In fact, the prior art teaches that polyclonal antibodies are well known to recognize proteins of distinct structural and functional characteristics. For example, Kelley *et al.* (Endocrine Research 16:477-491, 1990; see entire document; henceforth Kelley) and Chang *et al.* (J. Cell. Biol. 104:1563-1568, 1987; see entire

document; henceforth Chang) both teach that polyclonal antibodies against one protein are capable of recognizing a structurally and functionally different protein. Specifically, Kelley teaches that polyclonal antibodies against LH also recognize albumin (see for example the Abstract and Figures 1-2), and Chang teaches that antibodies to Vimentin and Desmin also recognize C-tektin and A-tektin (see for example the Abstract and the paragraph bridgin pages 1566-1567). Similarly, it can be expected that the polyclonal antibodies to SEQ ID NO: 1 of the instant specification will also cross-react with structurally and functionally distinct proteins. Thus, as per the teachings of the prior art and absent evidence to the contrary, the skilled artisan would not be able to envision which proteins that the SEQ ID NO: 1-based polyclonal antiboides bind to also have the necessary functional requirement to be a functional *F. nucleatum* RepA protein. Thus the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of functional *F. nucleatum* RepA proteins that can be recognized by polyclonal antibodies to SEQ ID NO: 1. In fact, the prior art teaches the unpredictability with trying to associate a structure-function relationship with the ability of a protein to be recognized by polyclonal antibodies. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 5, 7, 8, 12, 13, 21, 24, 25, 27, 30-32, 41, 44-47, 51-54, 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid, protein, plasmid or expression vector comprising or encoding a functional *F. nucleatum* RepA protein identified as SEQ ID NO: 1, does not reasonably provide enablement for a nucleic acid, protein, plasmid or expression vector comprising or encoding a functional *F. nucleatum* RepA protein having 80% or even 97% homology with SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This is a new rejection that is not necessitated by amendment.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is a nucleic acid, protein, plasmid or expression vector comprising or encoding a functional *F. nucleatum* RepA protein having 80% or even 97% homology with SEQ ID NO: 1. The instant specification does not teach what portions or domains of the protein identified as SEQ ID NO: 1 are required for its function. The instant claims are simply directed to a function-without-structure protein. This represents an invitation to the skilled artisan to experimentally and empirically identify those proteins having

80% or 97% homology with SEQ ID NO: 1 which also have the function of being an *F. nucleatum* RepA protein.

Scope of the invention. The scope of the invention is very broad, encompassing a number of proteins that may or may not have the ability to function as an *F. nucleatum* RepA protein. While the instant specification defines SEQ ID NO: 1 as such a protein, the instant specification does not teach what domains or portions of the protein are required for it to function as an *F. nucleatum* RepA protein. As a result, the skilled artisan cannot make proteins with 80% or 97% homology to SEQ ID NO: 1 that can also function as an *F. nucleatum* RepA protein.

State of the art and Level of skill in the art. The state of the art indicates that predicting function based on homology, similar to the manner that proteins having 80% or 97% homology to SEQ ID NO: 1 are claimed in the instant application, is unpredictable at best. Specifically, and as stated above in the rejection under Written Description, Everett *et al.* (*Nat. Gen.* **17**: 411-422, 1997; see entire document; henceforth Everett) first identified the Pendred gene product PDS, and predicted that PDS would function as a Sulphate-Ion transporter, based on its homology to known Sulphate-Ion transport proteins (see for example the Abstract and page 419, paragraph bridging the left and right columns to the second full paragraph, right column). However, Scott *et al.* (*Nat. Gen.* **21**: 440-443, 1999; see entire document; henceforth Scott) found that PDS was in fact not a Sulphate-Ion transporter despite its homology to known Sulphate-Ion transporters (see for example the Abstract and page 441, left column, third full paragraph). Rather, Scott found that PDS was a Chloride- and Iodide-Ion transporter, underscoring the importance of establishing a function for a protein despite homology with a protein of known-function (see for example the Abstract and page 441, left column, third full

paragraph). Thus, the skilled artisan would understand the unpredictability of associating a function to a protein based on sequence homology alone. Thus, in the absence of an identification of functional domains of SEQ ID NO: 1, the skilled artisan could not predictably make an *F. nucleatum* RepA protein that was 80% or 97% homologous to SEQ ID NO: 1.

Number of working examples and Guidance provided by applicant. The instant specification provides no guidance or working example that describe proteins having 80% or 97% homology to SEQ ID NO: 1 such that the skilled artisan would be able to make such a protein. The instant specification simply provides teachings regarding SEQ ID NO: 1, without the identification of a structure-function relationship for the protein such that the skilled artisan could make functional variants of SEQ ID NO: 1.

Unpredictability of the art and Amount of experimentation required art is highly unpredictable, requiring a great deal of undue and unpredictable trial and error experimentation in order to make and use the claimed invention. As established by the **State of the Art and Level of Skill in the Art**, the determination of function based simply on sequence homology is highly unpredictable. The instant specification does little to overcome this unpredictability by establishing a structure-function relationship for the protein identified as SEQ ID NO: 1 such that the skilled artisan could make variants of SEQ ID NO: 1 having as little as 80% or 97% homology to SEQ ID NO: 1 that maintain the ability to function as an *F. nucleatum* RepA protein. Instead, the skilled artisan would empirically have to determine what modifications could be made to SEQ ID NO: 1 while maintaining the ability to function as an *F. nucleatum* RepA protein, defining the functional domains of the protein by testing each mutation for its ability to maintain its function. Essentially, the claimed invention is an invitation to experiment

and find those proteins having 80% or 97% homology to SEQ ID NO: 1 that maintain the ability to function as an *F. nucleatum* RepA protein. Thus, the claimed invention is not enabled for the broad scope in which it is claimed.

Claims 5, 7, 8, 12, 13, 21, 24, 25, 27, 30-32, 41, 44-47, 51-54, 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid, protein, plasmid or expression vector comprising or encoding a functional *F. nucleatum* RepA protein identified as SEQ ID NO: 1, does not reasonably provide enablement for a nucleic acid, protein, plasmid or expression vector comprising or encoding a functional *F. nucleatum* RepA protein that is recognized by polyclonal antibodies raised against a protein identified as SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This is a new rejection that is not necessitated by amendment.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is a nucleic acid, protein, plasmid or expression vector comprising or encoding a functional *F. nucleatum* RepA protein that is recognized by polyclonal antibodies to a protein identified as SEQ ID NO: 1.

Scope of the invention. The scope of the invention is very broad, encompassing a huge number of nucleic acids, proteins, plasmids or expression vectors comprising or encoding proteins that can be recognized by polyclonal antibodies to SEQ ID NO: 1 due to the inherent cross-reactivity associated with polyclonal antibodies. The specification only teaches the protein identified as SEQ ID NO: 1 (which would inherently be recognized by polyclonal antibodies that are directed against it), and does not teach what other proteins that would be recognized by these polyclonal antibodies and retain the ability to function as an *F. nucleatum* RepA protein. As a result, the skilled artisan could not make the full scope of the nucleic acids, proteins, plasmids or expression vectors comprising or encoding a functional *F. nucleatum* RepA protein that is recognized by polyclonal antibodies to a protein identified as SEQ ID NO: 1.

State of the art and Level of skill in the art. The state of the art indicates that determining a structure-function relationship for a protein based upon its recognition by a polyclonal antibody is highly unpredictable. As indicated above in the rejection under Written Description, polyclonal antibodies are well known to recognize proteins of distinct structural and functional characteristics. For example, Kelley *et al.* (Endocrine Research 16:477-491, 1990; see entire document; henceforth Kelley) teaches that polyclonal antibodies against one protein are capable of recognizing a structurally and functionally different protein. Specifically, Kelley teaches that polyclonal antibodies against LH also recognize albumin (see for example the Abstract and Figures 1-2) which is not a functional equivalent of LH despite its recognition by antibodies to

LH. Similarly, it can be expected that the polyclonal antibodies to SEQ ID NO: 1 of the instant specification will also cross-react with structurally and functionally distinct proteins. Thus, the skilled artisan would be left to question which proteins that are recognized by polyclonal antibodies to the protein identified as SEQ ID NO: 1 are functional as an *F. nucleatum* RepA protein, based on the state of the art. As such, the skilled artisan could not make the full scope of the claimed invention.

Number of working examples and Guidance provided by applicant. The instant specification provides no guidance or working examples that would allow the skilled artisan to make a nucleic acid, protein, plasmid or expression vector comprising or encoding a functional *F. nucleatum* RepA protein that is recognized by polyclonal antibodies to a protein identified as SEQ ID NO: 1, aside from those comprising or encoding SEQ ID NO: 1 itself. There is no demonstration as to how to discern whether a protein that is recognized is a functional RepA protein or not. Thus, the instant specification cannot correct the unpredictability associated with the teachings of the prior art concerning the recognition of functionally unrelated proteins by polyclonal antibodies.

Unpredictability of the art and Amount of experimentation required. The claimed invention is highly unpredictable, requiring a great deal of unpredictable and undue trial and error experimentation. In order to make and use the claimed invention, the skilled artisan would first be required to identify each protein that is recognized by polyclonal antibodies to SEQ ID NO: 1, and then empirically determine whether or not the protein has the ability to function as a RepA protein in *F. nucleatum*. This is in essence an invitation to the skilled artisan to experiment by identifying and characterizing those proteins that are recognized by polyclonal antibodies to SEQ

ID NO: 1 with the hope of finding one or more proteins with the ability to function as a RepA protein in *F. nucleatum*. As a result, the invention is not enabled for the full scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "has" in the claim. The term "has" is not legally defined as "open" or "closed" language, and is therefore indefinite. **This rejection is maintained for reasons set forth in the previous Office Action.**

Claim 33 is rejected under 35 USC 112, second paragraph, as being indefinite for failing to recite a proper Markush group. In order for the claims to be definite, they must recite the proper Markush language, wherein the members of the Markush group are "selected from the group consisting of", followed by the listing of the members of the group. In addition, the conjunction "and" must follow the penultimate member of the group. In the instant case, it is unclear if the limitation includes the combination of (a) and (b) or (c), or if the limitation includes only one of (a), (b), or (c). **This is a new rejection that is not necessitated by amendment.**

Response to Arguments Concerning Claim Rejections - 35 USC § 112

Applicant's arguments filed March 22, 2002 concerning the rejection of claims 10, 33-36, 48 and 60 have been fully considered but they are not persuasive. Applicant's indicates that a deposit of the indicated plasmids/strains *will be made* upon the allowance of the instant claims. This is insufficient because a deposit of the plasmids/strains must be made in order to satisfy the requirements of 35 USC § 112, first paragraph. Thus, in the absence of proof of a biological deposit of pFN1, pFN2 and pFN3, the claims will remain rejected under 35 USC § 112, first paragraph.

Applicant's arguments filed March 22, 2002 concerning the rejection of claim 9 have been fully considered but they are not persuasive. Applicant indicates in their arguments that claim 9 has been amended to remove the "has" language. However, the amendment has apparently been inadvertently excluded from the most recent version of the claim amendments. As a result, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by McKay *et al.* (Plasmid 33:15-25, 1995; see entire document; henceforth McKay). **This rejection is maintained for reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 102

Applicant's arguments filed March 22, 2002 concerning claims 5, 7 and 8 have been fully considered but they are not persuasive. Applicant's arguments consist of the following points:

1. That McKay did not characterize their plasmids sufficiently to identify, distinguish and isolate individual plasmid components.

2. That applicant's detailed description of their plasmids is much better than McKay's superficial restriction analysis of a few naturally occurring plasmids.

3. That applicant's definition of "an isolated repA nucleic acid" as being ***separated*** (applicant's emphasis) from open reading frames that flank the repA gene distinguishes it from the McKay reference.

These arguments' are not convincing for the following reasons:

1. The level of characterization performed by McKay is irrelevant in light of the claimed invention. The fact of the matter is that McKay teaches an isolated nucleic acid (in the form of naturally occurring plasmids that are isolated for *F. nucleatum*), and this nucleic acid encodes a protein having 97.2% homology to SEQ ID NO: 1. This protein, being the same approximate length of SEQ ID NO: 1, will naturally have a molecular weight of about 44.8 kDa due to the fact that it has the same number of amino acid residues, which have about the same atomic weights. Furthermore, since the protein differs at only a few amino acids by (comparison of the protein sequences-see GenBank Accession No. AF022647, established September 3, 1997), polyclonal antibodies directed to SEQ ID NO: 1 would recognize the protein described by

McKay. Considering that McKay not only isolated the plasmid, but sequenced the plasmid, it is clear that McKay anticipates the instantly claimed invention.

2. The fact that the instant applicant characterizes their plasmids in more detail than the manner in which McKay characterizes their plasmid does not entitle them to claim the plasmid that has been characterized by McKay. The fact is that McKay describes the invention that is claimed in instant claims 5, 7 and 8, as evidenced by both the McKay reference and the sequence data (GenBank Acc. No. AF022647) generated from the plasmid described by McKay.

3. The term "an isolated repA nucleic acid" appears nowhere in the instantly rejected claims. Thus arguments concerning the definition of "an isolated repA nucleic acid" are moot. However, in the interest of clarifying the issue, the examiner wishes to point out that the alleged definition begins with the phrase "For example" when describing "an isolated repA nucleic acid." Thus, applicant's definition encompasses more than just the alleged "***separated*** (applicant's emphasis) from open reading frames that flank the repA gene" because that is simply one example of what is meant by "an isolated repA nucleic acid."

In conclusion, the rejection is maintained because applicant has not provided a convincing argument to withdraw the rejection.

Allowable Subject Matter

Claims 1-4, 11, 15-20, 26, 37-40, 49, 50, 55-57, 59 and 62 are allowed.

Claims 6, 9, 14, 22, 23, 28, 29, 42, 43 and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
AU 1636